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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/024,988	02/17/1998	RANDALL W. NELSON	5015C1	9007

20322 7590 12/16/2003

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EXAMINER

HOLLERAN, ANNE L

ART UNIT	PAPER NUMBER
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1642

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DATE MAILED: 12/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/024,988

Applicant(s)

NELSON ET AL.

Examiner

Anne Holleran

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-40 and 42-50 is/are pending in the application.
- 4a) Of the above claim(s) 32,34-39 and 42-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31,33,40 and 48-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Art Unit: 1642

DETAILED ACTION

1. Applicants' amendment filed September 3, 2003 is acknowledged. Claims 48-50 were added. Claims 31-40 and 42-50 are pending. Claims 32, 34-39 and 42-47, drawn to non-elected inventions, are withdrawn from consideration.

Claims 31, 33, 40 and 48-50 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections Maintained and New Grounds of Rejection:

3. The rejection of claims 31, 33 and 40 under 35 U.S.C. 102(b) as being anticipated by either Gaskell and Brownsey (Clin. Chem., 29(4): 677-680, 1983), Gaskell (Steroids, 55: 458-462, 1990), Bonfanti (Cancer Research, 50: 6870-6875, 1990) or Davoli (Anal. Chem., 65: 2679-2685, 1993) is maintained for the reasons of record.

Applicants' arguments have been considered but are unpersuasive. Applicant argues that each of the references fails to teach the claimed inventions. For each of the references, applicants argue that the references do not teach the claimed invention because the methods taught in the references require steps not recited in the claims. However, the claimed invention reads on methods that contain other purification steps, or contain a derivatization step, because the claimed methods are drawn to a methods "comprising" the steps recited in the claims. Thus, steps other than the ones specifically recited may be included in methods encompassed by the

Art Unit: 1642

claims. Applicants also argue that, because the method of collecting the mass spectrometry data is different from that taught in the specification, the references fail to teach the claimed inventions. However, this appears to be an argument for a limitation that is not present in the claims. The claims merely recite that the analyte is quantified using mass spectrometric analysis, and fails to specify a specific method for collecting the mass spectrometric data.

Claims 31, 33 and 40 are drawn to methods for quantifying an analyte in a specimen, comprising combining the specimen with an internal reference, then combining the specimen with an affinity reagent that binds both the analyte and the internal reference, and then quantifying the analyte using mass spectrometry. Claims 33 and 40 include a step that quantifying the analyte comprising comparing the ratio of the analyte spectra to the internal reference spectra to a standard curve. The internal standard is a modified analyte with shifted molecular weight and binds to the affinity reagent.

Gaskell and Brownsey teaches a method for quantifying estradiol-17 β , where a deuterated estradiol internal standard is added to a plasma sample, which is then mixed with solid-phase coupled antiserum specific for both the labeled and unlabeled estradiol. The extract is dried and analyzed by GC-MS. For quantitation, the ratios of the estradiol to deuterated estradiol were compared to a standard curve (page 678, first through second columns).

Gaskell teaches a method for quantifying DHA-S, where a deuterated DHA-S internal standard is added to a serum sample, which is then added to an immunoaffinity column. The immunoaffinity eluate was analyzed by gas-chromatography-mass spectrometry. For

Art Unit: 1642

quantification, the ratios of the DHA-S and deuterated internal standard are compared to a standard curve (page 460, first through second columns).

Bonfanti teaches a method for quantifying O⁶-butylguanine, where a deuterated internal standard is added to a serum sample, which is then loaded onto an immunoaffinity column. The immunoaffinity column eluate is analyzed by gas chromatography-mass spectrometry. For quantification, the ratios of the O⁶-butylguanine and deuterated internal standard were compared to a standard curve (page 6871, second column).

Davoli teaches a method for quantifying diethylstilbestrol, where deuterated internal standards are added to urine samples, which are then loaded onto immunoaffinity columns. The eluate was then analyzed by fast atom bombardment mass spectrometry. Quantification was made by comparison to a standard curve (page 2680, bottom of 2nd column – page 2681, and page 2685, first column).

Thus, either of Gaskell and Brownsey, Gaskell, Bonfanti or Davoli teaches the methods as claimed.

New Grounds of Rejection:

4. Claims 31, 33, 40 and 48-50 are rejected under 35 U.S.C. 102(a) as being anticipated by Nelson (Nelson, R.W. et al, Anal. Chem. 67: 1153-1158, 1995, April 1).

Claims 31, 33 and 40 are drawn to methods for quantifying an analyte in a specimen, comprising combining the specimen with an internal reference, then combining the specimen with an affinity reagent that binds both the analyte and the internal reference, and then quantifying the analyte using mass spectrometry. Claims 33 and 40 include a step that

quantifying the analyte comprising comparing the ratio of the analyte spectra to the internal reference spectra to a standard curve. The internal standard is a modified analyte with shifted molecular weight and binds to the affinity reagent. Claims 48-50 are drawn to methods that are the same as those of claims 31, 33 and 40, except that the analyte is a protein.

Nelson appears to teach a method that is the same as that claimed. It is noted that the publication date of Nelson is less than one year from the effective filing date of the instant application. However, the authorship of Nelson falls under the category of "another inventor", because it names inventors that are not named as co-inventors in the instant application. MPEP 2132 defines "another inventor" as any combination of authors or inventors different that the inventive entity of the application. The term "another" in 35 U.S.C. 102(a) refers to any entity which is different from the inventive entity. The entity need only differ by one person to be "by another".

5. Claims 31, 33, 40 and 48-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Lisek (Lisek, C.A. et al. Rapid Communications in Mass Spectrometry 3(2): 43-46, 1989; Abstract only).

To the extent that claims 31, 33 and 40 read on methods where the analyte is a protein, these claims are included in this rejection.

Lisek teaches a method in which substance P (an 11 amino acid peptide) is mixed with a deuterated internal standard form of substance P, then applied to an immunoaffinity column and then analyzed by mass spectrometry. Thus, Lisek teaches methods that are the same as that claimed.

Art Unit: 1642

Conclusion


No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:30 am to 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne L. Holleran
Patent Examiner
December 11, 2003


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